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PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/787,385	
	Filing Date	02/26/2004	
	First Named Inventor	Steven C. Quay	
	Art Unit	1623	
	Examiner Name		
Total Number of Pages in This Submission	6	Attorney Docket Number	03-02US

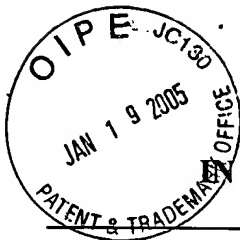
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Nastech Pharmaceutical Company Inc.		
Signature			
Printed name	Paul G. Lunn		
Date	January 14, 2005	Reg. No.	32,743

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Quay et al.

Serial No.: 10/787,385

Filed: 2/26/2004

Title: CYANOCOBALAMIN LOW  
VISCOSITY AQUEOUS  
FORMULATIONS FOR  
INTRANASAL DELIVERY

Group Art Unit: 1623

Attorney Docket No.: 03-02US

Commissioner for Patents  
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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

This Information Disclosure Statement is submitted:

- ☒ under 37 CFR 1.97(b), or  
(Within three months of filing national application; or date of entry of international application; or **before mailing date of first office action** on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:  
☐ Statement under 37 CFR 1.97(e), or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:  
☐ Statement under 37 CFR 1.97(e), and  
☐ a \$180.00 fee set forth in 37 CFR 1.17(p).  
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

☒ Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which

applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,



Paul G. Lunn  
Attorney/Agent for Applicant(s)  
Reg. No. 32743

Date: January 14, 2005


Telephone No.: (425) 908-3643  
Facsimile No. (425) 908-3655

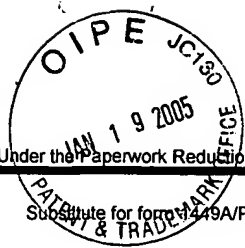
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/787,385	
			Filing Date	2/26/2004	
			First Named Inventor	Quay et al.	
			Art Unit	1623	
			Examiner Name		
Sheet	1	of	3	Attorney Docket Number	03-02US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Issued Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 2,703,302	03-01-1955	Merck & Co. Inc.	
		US- 2,703,303	03-01-1955	Merck & Co., Inc.	
		US- 2,746,796	05-22-1956	The Pharma-Craft Corporation	
		US- 2,914,222	11-24-1959	Philip Meshberg	
		US- 3,000,793	09-19-1961	Merck & Co., Inc.	
		US- 2,951,017	08-30-1960	The Distillers Company Limited	
		US- 3,057,851	10-09-1962	Armour Pharmaceutical	
		US- 3,018,225	01-23-1962	Merck & Co., Inc.	
		US- 3,120,509	02-04-1964	Hoffmann-La Roche Inc.	
		US- 3,282,781	11-01-1966	Merck & Co., Inc.	
		US- 3,548,057	12-15-1970	Merck & Co., Inc.	
		US- 3,577,537	05-04-1971	Merck & Co., Inc.	
		US- 3,584,115	06-08-1971	Arthur I. Gebhart & Angelo T. Bonduris	
		US- 3,957,966	05-18-1976	GAF Corporation	
		US- 4,174,295	11-13-1979	Montedison S.p.A.	
		US- 4,523,341	06-25-1985	Mayo Pharmaceutical Laboratories	
		US- 4,724,231	02-09-1988	Nastech Pharmaceutical, Inc.	
		US- 5,801,161	09-01-1998	Merkus, Franciscus	
		US- 5,797,390	08-25-1998	McSoley, Thomas E.	
		US- 5,925,625	07-20-1999	Merkus, Franciscus	
		US- 6,665,421	12-16-2003	Image Therm Engineering, Inc.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 0131315 A2	02-15-1984	Istituto De Angeli		
		EP 0130550 A2	06-27-1984	Intermedical GmbH		
		PCT WO 86/05988 (International Application Number PCT/US86/00793)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		
		PCT WO 86-05987 (International Application Number PCT/US86/00665)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 3

**Complete if Known**

Application Number	10/787,385
Filing Date	2/26/2004
First Named Inventor	Quay et al.
Art Unit	1623
Examiner Name	
Attorney Docket Number	03-02US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		RAYMOND W. MONTO, JOHN W. REBUCK, MICHAEL BRENNAN, Crystalline B <sup>12</sup> Inhalation Therapy in Pernicious Anemia, The American Journal of the Medical Sciences, 2-1953, Pages 113-119, Publisher: Division of Hematology and Department of Laboratories, The Henry Ford Hospital, Detroit, Michigan Published in: Detroit, MI, US	
		RAYMOND W. MONTO, JOHN W. REBUCK, Nasal Instillation and Inhalation of Crystalline Vitamin B <sup>12</sup> in Pernicious Anemia, A.M.A. Archives of Internal Medicine, Volume 93, 1954, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebeck), The Henry Ford Hospital. Pages 219-230. Detroit, MI, US.	
		RAYMOND W. MONTO, JOHN W. REBUCK, Observations on the Mechanism of Intranasal Absorption of Vitamin B <sup>12</sup> in Pernicious Anemia. Blood, Volume 10, 1955, pages 1151-1155, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebeck), The Henry Ford Hospital. Detroit, MI, US.	
		A. KILLANDER AND I. WERNER, Studies on Maintenance Treatment of Pernicious Anaemia, Vitamin B <sup>12</sup> and Intrinsic Factor Europaisches Symposium Hamburg, 1961, Pages 663-667, Ed. H.c. Heinrich, Enke, Stuttgart, Department of Pediatrics and Internal Medicine, Akademiska, Sjukhuset, Uppsala, Sweden	
		N.K. SHINTON AND A.K. SINGH, Vitamin B <sup>12</sup> absorption by inhalation, Chemical Abstracts, Volume 66, Number 15, Coden: Chaba8, The American Chemical Society, 4/10/1967, Page 6024, Abstract 64246(e) Northampton Sts, Easton, PA, US.	
		N.K. SHINTON AND A.K. SINGH, Vitamin B <sup>12</sup> Absorption by Inhalation, Brit. J. Haemat, 1967, 13. Pages 75-79, Department of Haematology, Coventry and Warwickshire Hospital, Coventry	
		FOREST LABORATORIES, INC., Long Acting oral carrier, Chemical Abstracts, Volume 77, Year 1972, Page 263, Abstract 105623(y)	
		SALLY MATHISON, RAKESH NAGILLA, AND UDAY B. KOMPPELLA, Nasal Route for Direct delivery of Solutes to the Central Nervous System: Fact or Fiction? Journal of Drug Targeting, 1998, Volume 5, No. 6, pages 415-441 Department of Pharmacol Science, Department of Chemistry, Auburn University, Auburn, AL US	
		ANTHONY J. CUTIE AND JOHN J. SCIARRA, Intranasal Pharmaceutical Aerosols, Aerosol Age, The International authority in Spray Packaging, Aerosol Age Magazine, 10/1982, Pages 1-4	
		R.K. CHANDRA, GLORIA HERESI, AND G. WOODFORD, Double-blind controlled crossover trial of 4% intranasal sodium cromoglycate solution in patients with seasonal allergic rhinitis, Annals of Allergy, 09/1982, Volume 49, From the Department of Pediatrics, Memorial University of Newfoundland, Janeway Child Health Center and Health Sciences Center, St. John's, Newfoundland, Canada	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	10/787,385
			<b>Filing Date</b>	2/26/2004
			<b>First Named Inventor</b>	Quay et al.
			<b>Art Unit</b>	1623
			<b>Examiner Name</b>	
(Use as many sheets as necessary)			<b>Attorney Docket Number</b>	03-02US
Sheet	3	of	3	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Edited by JAMES E.F. REYNOLDS, Cyanocobalamin, Martindale, The Extra Pharmacopoeia, 1982, Abstract 7853-d, and Page 1645, Cyanocobalamin Injection, 28 <sup>th</sup> Edition, Published by direction of the Council of The Pharmaceutical Society of Great Britain and prepared in the Society's Department of Pharmaceutical Sciences, The Pharmaceutical Press, London, UK	
		CHENG DER YU, RICHARD JONES, JIM WRIGHT, AND MAIDA HENESIAN, Characterization of dose delivery and spray pattern of a metered-dose flunisolide nasal spray, Drug development and Industrial Pharmacy, 1983, 9(3), Pages 473-483, Institute of Pharmaceutical Sciences, Syntex Research, Palo Alto, CA Marcel Dekker, Inc., US	
		ANWAR A. HUSSAIN, YUKIHIKO ARAMAKI, Studies on the Intranasal Absorption of vitamin B <sup>12</sup> in the Rat, Final Report, 12/1984, University of Kentucky, College of Pharmacy, Lexington, KY, US	
		Valois, Pumps for Pharmacy, Year Unknown (product brochure)	
		JOHN J. SIARRA, Aerosols, Chapter 92, Year Unknown, Pages 1614-1621, Arnold & Marie Schwartz Collet of Pharmacy and Health Sciences, Long Island University, Brooklyn, NY, US	
		T.Q.NIJST, R.A. WEVERS, H.C. SCHOONDERWALDT, O.R. HOMMES, A.F.J. DE HAAN, Vitamin B12 and folate concentrations in serum and cerebrospinal fluid of neurological patients with special reference to multiple sclerosis and dementia, Journal of Neurology, Neurosurgery, and Psychiatry, Year 1990; 53, Page 951-954	
		GARCIA-ARIETA, A.; TORRADO-SANTIAGO, S.; GOYA, L.; TORRADO, J. J., Spray-dried powders as nasal absorption enhancers of cyanocobalamin, Biol.Pharm.Bull, date- 2001, Volume 24, issue- 12, Pages 1411-1416, Pharmaceutical Society of Japan	
		U.S. DEPARTMENT OF HEALTH AND HUMANS SERVICES, Guidance for Industry, Nasal spray and inhalation solution, suspension, and spray drug products-chemistry, manufacturing, and controls documentation, 07/2002, Pages 1-44, Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, MD, US	

Examiner Signature	Date Considered
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